			PATENT Attorney Docket No. 19799-206
IN THE UNITED STATES PATENT AND TRADEMARK OFFICE			
APPLICANTS:	Jacques, Steven	CONFIRMATION NO.:	9597
APPLICATION NO.:	10/698,496	GROUP NO.:	3731
FILING DATE:	October 31, 2003	EXAMINER :	Nguyen, Tuan Van
TITLE:	LOW PROFILE SHORT TAPERED TIP CATHETER		

Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

DECLARATION UNDER 37 C.F.R. § 1.132

Sir:

I, Harold M. Aznoian, hereby declare and say:

1. I am Vice President of New Product Development at ConMed Endoscopic Technologies, a wholly-owned subsidiary of ConMed Corporation.

2. On September 30, 2004, ConMed Corporation acquired certain assets of C. R. Bard, Inc., including but not limited to U.S. Patent Application No. 10/698,496 ("the '496 Application"). On June 28, 2005, C.R. Bard, Inc. assigned the '496 Application to ConMed Endoscopic Technologies, Inc. The assignment is recorded at Reel/Frame No. 016669/0054.

3. I was employed by C. R. Bard, Inc. ("Bard") from 1986 to 2004, which included a variety of positions in the endoscopic technologies field, culminating with my position as Vice President of R&D for Bard Endoscopic Technologies. Over this time period, I became very familiar with the needs of endoscopists and endoscopic surgeons, endoscopic product innovation, and the marketplace of competitive products. Steven Jacques, the named inventor on the '496 Application, was a Senior Project Engineer in my department at the time he made the inventions described in the '496 Application.

4. Independent claim 14 in the '496 Application, as currently amended, is directed to a catheter comprising, among other things, a shaft comprising "two or more lumens, at least one

of which is sized to receive a 0.035 inch guidewire;" a tip at the distal end of the shaft having a tapered portion ending in a distal terminus, wherein the tapered portion has a length of "approximately 3 millimeters or less;" and the distal terminus has an outer diameter measuring "less than approximately 0.063 inch."

5. Independent claim 26 is directed to a catheter comprising, among other things, a shaft comprising "two or more lumens, at least one of which is sized to receive a 0.035 inch guidewire;" a tip at the distal end of the shaft having a tapered portion ending in a distal terminus, wherein the tapered portion has a length "within the range of 1.5 mm to 4.5 mm;" and the distal terminus has an outer diameter measuring "within the range of 0.055 inch to 0.063 inch."

6. Marketplace Prior to the '496 Application Priority Date (November 1, 2002).

(a) I am unaware of any commercial competitor who had, prior to November 1, 2002, a multi-lumen catheter with a 0.035 inch guidewire-compatible lumen, a distal tip having a short tapered portion as defined in the '496 claims, and a low profile distal terminus, as defined in the '496 claims.

(b) The 2002 product catalog from Boston Scientific/Microvasive includes two "Autotome™ RX" triple lumen sphincterotomes specifying tip outer diameters of "<5" (Order Numbers M00545150 and M00545160). Exhibit A at page 4. The catalog also includes other RX sphincterotomes specifying tip outer diameters of "sub 5." Exhibit A at page 5. To a person with endoscopic industry knowledge and experience such as myself, the terms "<5" and "sub 5" strongly suggest that Boston Scientific/Microvasive did not have real, measurable outer diameters below 5 French. These terms are the sort of terms that marketing professionals employ when a verifiable claim cannot be made as to actual outer diameter measurements. My understanding of these terms is supported by the fact that in the following year, 2003, the Boston Scientific/Microvasive catalog provides for the first time actual outer diameter measurements for the RX sphincterotomes. Exhibit B.

(c) I also note that in the 2002 Boston Scientific/Microvasive catalog, guidewire compatibility specifications are not provided for many of the RX spincterotomes, and taper length is not provided for any of them. Exhibit A at pages 4 and 5.

(d) The 2002 Boston Scientific/Microvasive catalog discloses other sphincterotomes having larger distal tips (5 F and 5.5 F) and 0.035 inch guidewire compatibility. Also, the Tapertome™ Single-Use Sphincterotome had a 3.5 F tip, but was not compatible with a 0.035 inch guidewire (a 0.025 inch guidewire is recommended). Exhibit A at pages 6-8.

(e) The 2002 product catalog from Wilson Cook disclosed a variety of Dash™ spincterotomes with distal tips ranging from 3.0 French to 5.5 French. Only the 5.5 French sphincterotome is specified as compatible with an 0.035 inch guidewire. The smaller tipped devices require smaller guidewires. Exhibit C.

7. In approximately February of 2003, Bard launched the new Apollo AC (double lumen) and Apollo 3AC (triple lumen) advanced cannulation papillotomes. According to Boston Scientific product literature, the Autotome RX sphincterotomes were available in 2003 in the following sizes:

Number	Name	Cut-Wire (mm)	Tip Length (mm)	Tip O.D. (Fr)	Recommended Guidewire (in)
M00545150	Autotome RX 49	20	5	4.9	.035"
M00545160	Autotome RX 49	30	5	4.9	.035"
M00545170	Autotome RX 44	20	5	4.4	.035"
M00545180	Autotome RX 44	30	5	4.4	.035"
M00545190	Autotome RX 39	20	5	3.9	.025"
M00545200	Autotome RX 39	30	5	3.9	.025"

See Exhibit B. There is an important distinction between the Autotome RX Cannulating Sphincterotomes and the Bard Apollo AC 4.5 F papillotomes. As noted in Exhibit D, the Autotome RX 44 and 39 models feature Merging Lumen Technology™. In this Technology, the contrast lumen is merged with the guidewire lumen so that there is a single port exiting the distal tip of the device. The single port contains both the guidewire and contrast media. This feature is disadvantageous in that when contrast media is delivered through the same lumen that contains the guidewire, flow resistance is increased, which results in reduced injection speed and volume. In a clinical setting, it is important to be able to inject contrast media with speed and volume so as to minimize the time that the patient is exposed to fluoroscopy and to provide the physician with a view of the biliary tree as quickly as possible. In addition, guidewire maneuverability is reduced when the guidewire comes in contact with the highly viscose contrast media. Bard's Apollo AC 4.5 F papillotomes had two separate lumens (of a 3-lumen extrusion) that ran the

entire length of the instrument through the distal tip – one was dedicated for contrast media and the other was dedicated for the guidewire. The ConMed Apollo AC 4.5 F papillotomes sold today maintain the same two dedicated lumens all the way through the distal tip of the instrument. Consequently, contrast media injection and guidewire maneuverability are not compromised in the Apollo AC 4.5 F papillotomes. A side-by-side photographic comparison of the Boston Scientific Autotome RX 44 and the ConMed Apollo 3 AC papillotomes is attached as Exhibit E.

8. The creation of a multi-lumen catheter having a 0.035 inch guidewire-compatible lumen, a distal tip having a short tapered portion as defined in the '496 claims, and a low profile distal terminus, as defined in the '496 claims, was a very difficult design challenge. The inventor of the '496 Application, Steven Jacques, tried, but failed to create such a device using existing technology. The design attributes of the claimed invention were not attainable with traditional design and manufacturing techniques. Ultimately, Jacques had to invent a variety of significant changes and improvements to existing design and manufacturing techniques in order to reduce to practice the claimed invention. For example, based on my knowledge and understanding of the endoscopic design field:

(a) traditional manufacturing methods did not allow for the ability to prevent heating of unintended adjacent areas of the shaft. This degree of control is required in order to keep the tip short while achieving a lower profile outside diameter over a shorter taper length;

(b) traditional manufacturing methods did not allow for a proximal and distal clamp design in connection with mandrels during the necking process to correctly form the distal profile;

(c) conventional manufacturing methods did not provide for the particular heating, cooling, and pulling process designed and utilized by Jacques; and

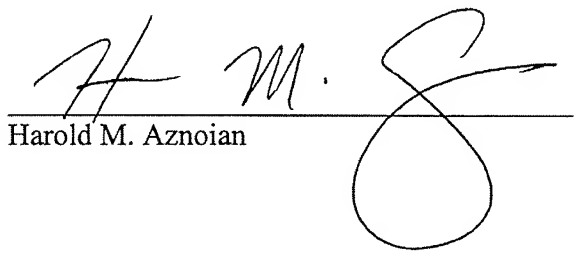
(d) conventional papillotome manufacturing methods did not allow for a shortened radiopaque slug or a shortened split collet for the cutting wire. The shortened

slug and the shortened split collet help to maximize the amount of polymer material at the distal tip for tapering while anchoring the cutting wire and providing an adequate radiopaque marker. See Paragraphs 0046-0049 of the '496 Application.

In my opinion, these design innovations surpassed the level of ordinary skill in the art.

9. I further declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further, that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent resulting therefrom.

11.30.07
Date



Harold M. Aznoian

EXHIBIT A

2002

PRICE LIST

AND ORDERING

INFORMATION

PRODUCTS FOR

ENDOSCOPY

Boston Scientific
MICROVASIVE®

Table of Contents

PRODUCT GUIDE 1

RX BILIARY SYSTEM™

RX Cannulas
- ***NEW*** Alien™ RX Single-Use Microcannula ..3
- Microvasive RX Single-Use Cannulas 3

RX Guidewires
- Extendable Jagwire™ Single-Use Guidewires .4
- Jagwire Single-Use Guidewires 4

RX Sphincterotomes
- RX Single-Use Tapertome™ Sphincterotome 4
- RX Single-Use Cannulating Sphincterotome 4
- RX Single-Use Sphincterotome 4
- RX Single-Use Triple-Lumen Needleknife XL 4

RX Stone Retrieval
- Microvasive RX Single-Use Biliary Retrieval Balloons - Distal Injection 5
- Microvasive RX Single-Use Biliary Retrieval Balloons - Proximal Injection 5

RX Dilatation
- ***NEW*** Hurricane™ RX Single-Use Dilatation Balloons 5

RX Cytology
- Microvasive Single-Use RX Cytology Brush 5

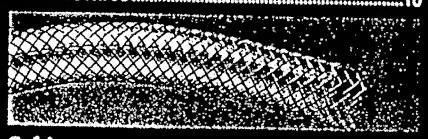
RX Plastic Stents
- Microvasive Single-Use RX Plastic Biliary Stents 6

RX Accessories
- Accessories 6

BILIARY

Cannulas
- Tandem™ XL Single-Use Triple-Lumen ERCP Cannula 7
- Contour™ Single-Use ERCP Cannula 7
- Fluoro Tip™ Single-Use ERCP Cannulas 8

Guidewires
- Jagwire Single-Use High Performance Guidewires 9
- Zebra® Single-Use Exchange Guidewires 9
- Amplatz Super Stiff® Single-Use Guidewires 9
- Glidewire® Single-Use Guidewires 10
- Pathfinder™ Single-Use Exchange Guidewires 10



Sphincterotomes
- Microknife™ XL Single-Use Triple-Lumen Needleknife 11
- Tapertome Single-Use Sphincterotome 11
- Stonetome™ Single-Use Stone Removal Device 11
- Ultratome XL™ Single-Use Triple-Lumen Wireguided Sphincterotome 12
- Fluorotome™ Single-Use Double-Lumen Wireguided Sphincterotome 12
- Ultratome™ Single-Use Double-Lumen Wireguided Sphincterotome 13

Stone Retrieval
- Extractor XL™ Triple-Lumen Single-Use Retrieval Balloons (Distal Injection) 14
- Extractor™ Triple-Lumen Single-Use Retrieval Balloon Catheters (Proximal Injection) 14
- Double-Lumen Single-Use Retrieval Balloons 14
- Monolith™ Single-Use Single-Piece Mechanical Lithotripter 15

Positrap™ Retrievers
- Positrap Single-Use Mini Retrieval Baskets 15

Biliary Dilatation
- Maxforce™ Single-Use Biliary Dilatation Balloons 16
- Passage™ Single-Use Biliary Dilatation Catheters (Graduated) 16

Biliary Cytology
- Combo Cath™ Single-Use Wireguided Biliary Cytology Brush 17

Metal Stents
- Wallstent® Single-Use Biliary Endoprosthesis with Permalume® Covering and Unistep™ Plus Delivery System 18
- Wallstent Single-Use Biliary Endoprosthesis with Unistep Plus Delivery System 18
- Ultraflex™ Diamond™ Single-Use Biliary Stent System 18

Biliary Plastic Stents
- Flexima™ Single-Use Biliary Stent System 19
- Solopass™ Percuflex® Single-Use Biliary Stent System 20
- Percuflex Amsterdam Single-Use Biliary Stents 20
- Percuflex Amsterdam Single-Use Stent Introducer Kits 21
- Percuflex Amsterdam Single-Use Biliary Stent with Introducer Kits 21
- C-Flex® Single-Use Pigtail Biliary Stents 22
- C-Flex Single-Use Pigtail Stent Introducer Kits 22
- C-Flex Single-Use Pigtail Stent with Introducer Kits 22

Biliary Accessories
- Single-Use Biliary Accessories 23
- Active Cords (Fit Microvasive Endoscopy Sphincterotomes) 23

METAL STENTS

Esophageal Stents
- Ultraflex Single-Use Covered Esophageal Stent Systems – Distal Release 25
- Ultraflex Single-Use Covered Esophageal Stent Systems – Proximal Release 25
- Ultraflex Single-Use Covered Large Esophageal Stent Systems – Distal Release 25
- Ultraflex Single-Use Covered Large Esophageal Stent Systems – Proximal Release 25
- Ultraflex Single-Use Noncovered Esophageal Stent Systems – Distal Release 26
- Ultraflex Single-Use Noncovered Esophageal Stent Systems – Proximal Release 26
- Wallstent Single-Use Esophageal II Endoprosthesis (with Permalume® Covering) 26

Biliary Stents
- Wallstent® Single-Use Biliary Endoprosthesis with Permalume Covering and Unistep Plus Delivery System 27
- Wallstent Single-Use Biliary Endoprosthesis with Unistep Plus Delivery System 27
- Ultraflex Diamond Single-Use Biliary Stent System 27

Tracheobronchial Stents
- Ultraflex Single-Use Noncovered Tracheobronchial Stent System – Distal Release 28
- Ultraflex Single-Use Noncovered Tracheobronchial Stent System – Proximal Release 28
- Ultraflex Single-Use Covered Tracheobronchial Stent System – Distal Release 29
- Wallstent Single-Use Tracheobronchial Endoprosthesis with Permalume Covering and Unistep Plus Delivery System 29

Colonic and Duodenal Stents
- Wallstent Single-Use Colonic and Duodenal Endoprosthesis with Unistep Plus Delivery System 30
- Wallstent Single-Use GI Guidewire 30

DILATATION

CRE™ Controlled Radial Expansion Balloon Dilators
- Single-Use CRE Fixed Wire Balloon Dilators 33
- Single-Use CRE Wireguided Esophageal/Pyloric Balloon Dilators 33
- Single-Use CRE Wireguided Esophageal/Pyloric/Colonic Balloon Dilators 34

Maxforce TTS Single-Use Balloon Dilators
- Single-Use Maxforce Esophageal Balloon Dilators 34
- Single-Use Maxforce Esophageal Balloon Dilator Multipacks and Kits 35

Rigiflex® ABD Achalasia Balloon Dilators
- Single-Use Rigiflex Achalasia Balloon Dilators 35

Hurricane Single-Use RX Biliary Dilatation Balloons
- ***NEW*** Hurricane RX Single-Use Dilatation Balloons 36

Maxforce Single-Use Biliary Dilatation Balloons
- Single-Use Maxforce Biliary Dilatation Balloons 36

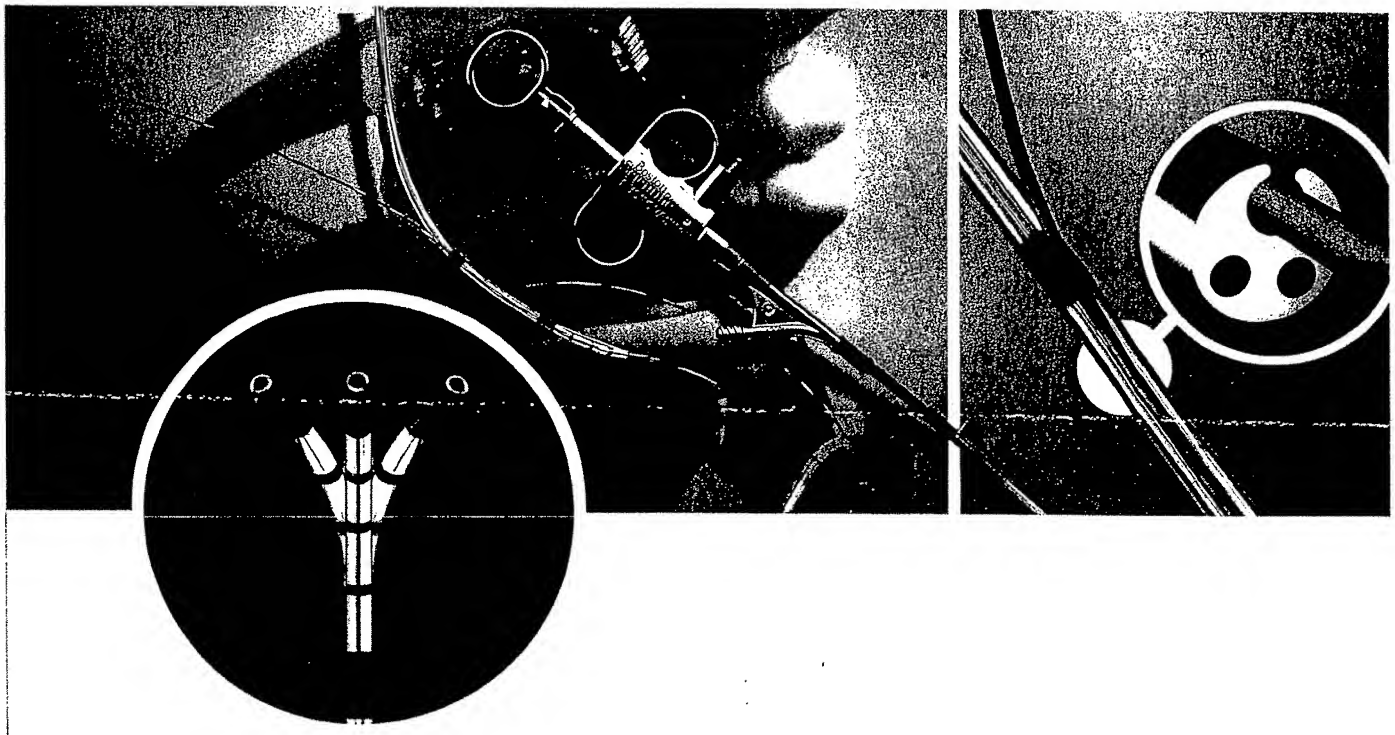
Inflation Systems
- Alliance™ II Integrated Inflation System 37
- Leveen™ Inflation System 37
- ***NEW*** Breeze™ RX Inflation System 37

Dilatation Accessories
- Inflation/Deflation Devices and Accessories .37

2002

Autotome™ RX

Rotatable Cannulating Sphincterotome

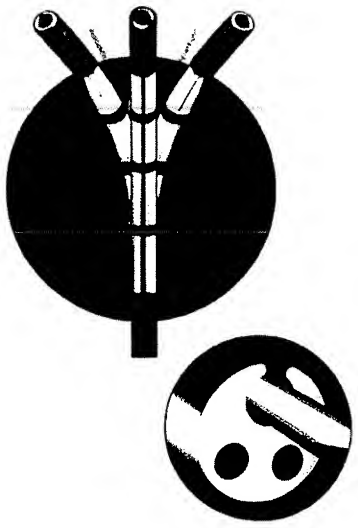


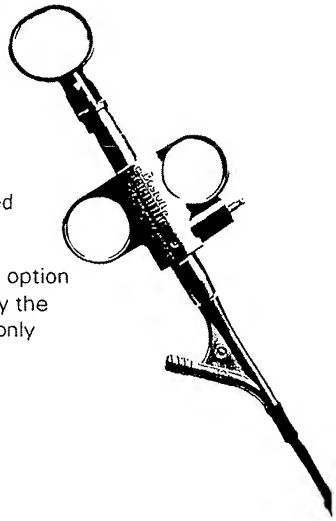
Boston Scientific
MICROVASIVE®

Take control... Autotome™ RX

2002

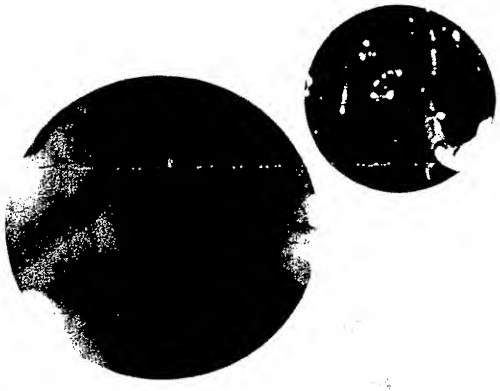
Introducing the first RX compatible rotatable sphincterotome.





Controlled Direction

- **Direct Wire Technology™:** new design allows rotation of cutting wire to the left or right.†
- **Rotating Handle:** improved ergonomics and controlled tip rotation.
- **2nd Generation "C" Groove Technology:** offers the option of independent guidewire manipulation and locking, by the physician, whilst reducing over-the-wire exchange to only 6cm of the total device length.
- **Open Lumen Design:** conforms to standard 3 lumen over-the-wire techniques, but may be converted to RX compatible techniques and devices at anytime.



Controlled Outcomes

- **Orientation of Tip:** aides in gaining access to the papilla and increases control of sphincterotomy in complex anatomical situations.*
- **Selective Wire Cannulation:** made easier by left to right tip movement and independent wire control:
  - ✓ Through tortuous anatomy
  - ✓ Past difficult strictures
  - ✓ Hilar or Pancreatic access

Ordering Information

Order Number	Description	Cutting Wire Length (mm)	Tip Length (mm)	Tip O.D. (Fr)	Guidewire (in)
M00545150	Autotome™ RX	20	5	<5	0.035**
M00545160	Autotome™ RX	30	5	<5	0.035**

MICROVASIVE RAPID EXCHANGE BILIARY SYSTEM

Note: Autotome™ RX is compatible with universal active diathermy cords

* Data on file Boston Scientific Corporation

** Recommended Guidewire 260cm or 450cm Jagwire™

† Patents pending

Boston Scientific
MICROVASIVE®

Freephone from Sweden:
Tel: 020 65 25 30 Fax: 020 55 25 35
Freephone from Finland:
Tel: 09 622 42 65 Fax: 09 622 42 66
Freephone from Denmark:
Tel: 80 30 80 02 Fax: 80 30 80 05
Freephone from Norway:
Tel: 80 010 404 Fax: 80 010 190
Freephone from Belgium:
Tel: 080094 494 Fax: 080093 343

Boston Scientific Nordic AB
Berga Allé 1
25452 Helsingborg
Sweden
Tel: +46 42 25 6900
Fax: +46 42 16 2477

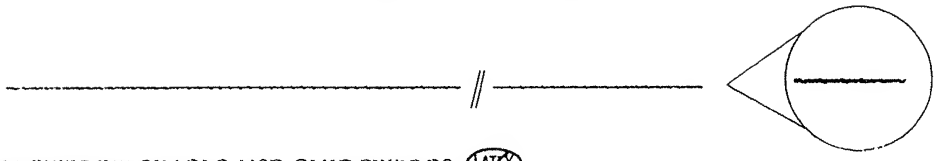
Boston Scientific Int. B.V.
Gaetano Martinolaan 50
PO Box 1363
6201 BJ Maastricht
The Netherlands
Tel: +31 43 356 8260
Fax: +31 43 356 8265

Boston Scientific Limited
New England House
Sandridge Park, Porters Wood
St. Albans, Herts. AL3 6PH. UK.
Tel: +44 1727 866633
Fax: +44 1727 830371

2002

RX BILIARY SYSTEM™

RX GUIDEWIRES



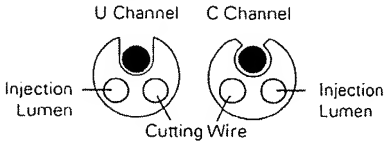
■ EXTENDABLE JAGWIRE™ SINGLE-USE GUIDEWIRES (LATEX)

Order Number	Description	O.D. (in)	Length (cm)	Tip Style	Price (Box 2)
M00556840	Extendable Jagwire RX Guidewire	.035	260	Straight tip	$299 bx
M00556850	Extendable Jagwire RX Guidewire	.035	260	Angled tip	$299 bx
M00556860	Stiff Shaft Extendable Jagwire RX Guidewire	.035	260	Straight tip	$299 bx
M00556870	Stiff Shaft Extendable Jagwire RX Guidewire	.035	260	Angled tip	$299 bx
M00556900	Jagtail™	.035	200	Guidewire extension	$450 bx

■ JAGWIRE™ SINGLE-USE GUIDEWIRES (LATEX)

Order Number	Description	O.D. (in)	Length (cm)	Tip Style	Price (Box 2)
M00556460	Jagwire	.025	260	Straight tip	$229 bx
M00556480	Stiff Shaft Jagwire	.025	260	Straight tip	$229 bx
M00556490	Stiff Shaft Jagwire	.025	260	Angled tip	$229 bx

RX SPHINCTEROTOMES



■ RX SINGLE-USE TAPERTOME™ SPHINCTEROTOME (LATEX)

Order Number	Description	Cut Wire (mm)	Tip Length (mm)	Channel	Tip Diameter (Fr)	Price
M00532850	RX Tapertome™, Short Nose	20	5	C	sub 4	$199 ea
M00532860	RX Tapertome™, Short Nose	30	5	C	sub 4	$199 ea

■ RX SINGLE-USE CANNULATING SPHINCTEROTOME (LATEX)

Order Number	Description	Cut Wire (mm)	Tip Length (mm)	Channel	Tip Diameter (Fr)	Price
M00545050	RX Cannulating Sphincterotome, Short Nose	20	5	C	sub 5	$199 ea
M00545060	RX Cannulating Sphincterotome, Short Nose	30	5	C	sub 5	$199 ea

■ RX SINGLE-USE SPHINCTEROTOME (LATEX)

Order Number	Description	Cut Wire (mm)	Tip Length (mm)	Channel	Tip Diameter (Fr)	Price
M00545500	RX Sphincterotome, Short Nose	20	5	U	sub 5	$199 ea
M00545510	RX Sphincterotome, Short Nose	30	5	U	sub 5	$199 ea
M00545520	RX Sphincterotome, Long Nose	20	20	U	sub 5	$199 ea
M00545530	RX Sphincterotome, Long Nose	30	20	U	sub 5	$199 ea

■ SINGLE-USE TRIPLE-LUMEN NEEDLEKNIFE XL (LATEX)

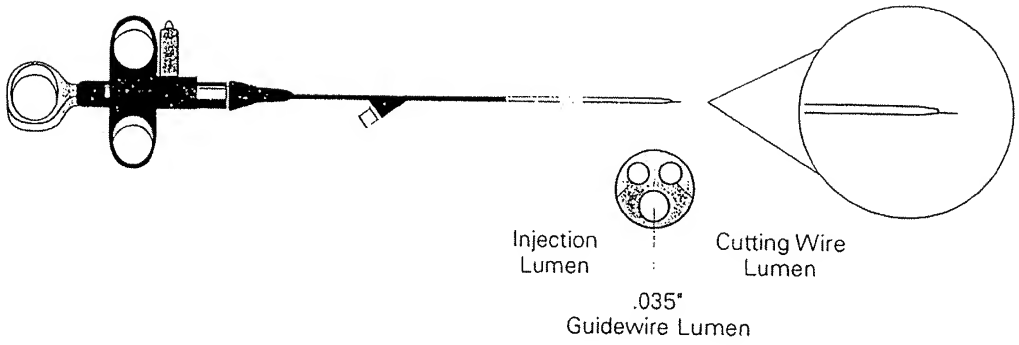
Order Number	Description	Cut Wire (mm)	Tip Length (mm)	Channel	Tip Diameter (Fr)	Price
M00545840	RX Needleknife XL	5	5	C	Sub 5	$199 ea

(LATEX)

2007

BILIARY

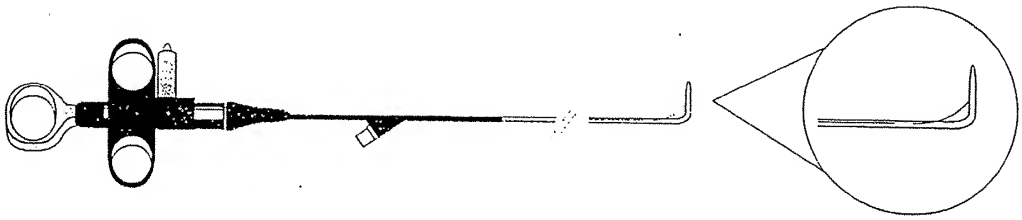
SPHINCTEROTOMES



■ MICROKNIFE™ XL SINGLE-USE TRIPLE-LUMEN NEEDLEKNIFE (LATEX)

Order Number	Description	Shaft O.D. (Fr)	Catheter Length (cm)	Recommended Guidewire (in)*	Pri
M00532810	MicroKnife XL	7.0 - 5.0	200	.035	$149

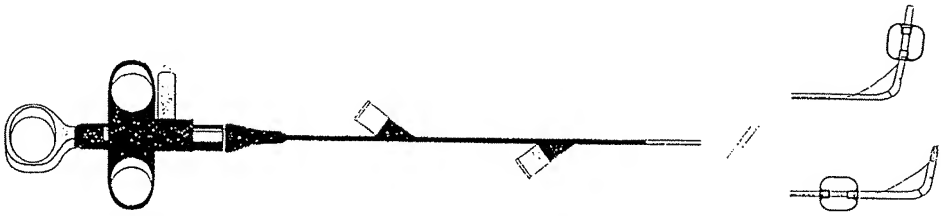
* Recommended Guidewire .035" Jagwire Guidewire, Order #5658 or #5659 (see page 9).



■ TAPERTOME™ SINGLE-USE SPHINCTEROTOME (LATEX)

Order Number	Description	Shaft O.D. (Fr)	Catheter Length (cm)	Tip O.D. (Fr)	Cut Wire (mm)	Recommended Guidewire (in)*	Pri
M00532820	Tapertome	7.0 - 5.5	200	3.5	20	.025	$189 e

* Recommended Guidewire .025" Jagwire Guidewire, Order #5656 (see page 9).



■ STONETOME SINGLE-USE STONE REMOVAL DEVICE

Order Number	Description	Balloon Diameter (mm)	Catheter Length (cm)	Tip Length (mm)	Cut Wire (mm)	Recommended Guidewire (in)*	Pric
M00535150	[illegible]	11.5	200	5	20	035	$329 e.
M00535170	[illegible]	11.5	200	20	20	035	$329 e.
M00535190	[illegible]	11.5	200	5	30	035	$329 e.
M00535210	[illegible]	11.5	200	20	30	035	$329 e.
M00535110	[illegible]	11.5	200	20	20	035	$329 e.
M00535130	[illegible]	11.5	200	20	30	035	$329 e.

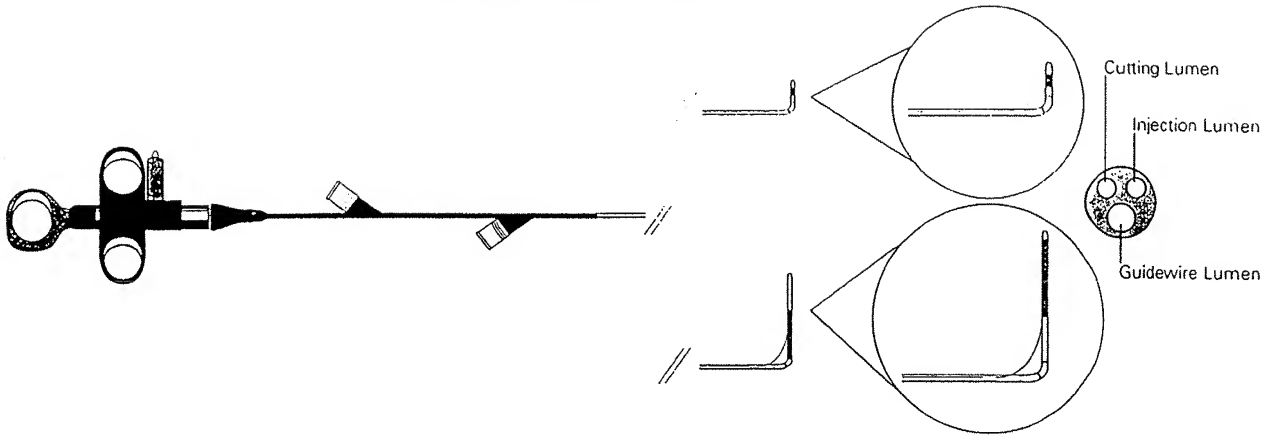
* Recommended Guidewire [illegible] (see page 9).
Note: Guidewire sold separately (see page [illegible]).

(LATEX) [illegible]

2002

BILIARY

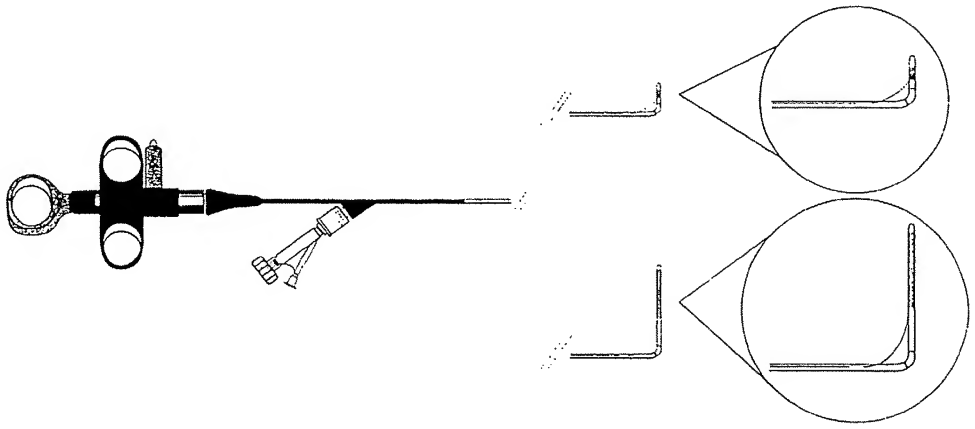
SPHINCTEROTOMES



■ ULTRATOME XL™ SINGLE-USE TRIPLE-LUMEN WIREGUIDED SPHINCTEROTOME (LATEX)

Order Number	Description	Cutting Wire Length (mm)	Distal O.D. (mm)	(Fr)	Catheter Length (cm)	Recommended Guidewire (in)*	Price
M00535900	Ultratome XL Short Nose	20	1.8	5.5	200	.035	$199 ea
M00535910	Ultratome XL Long Nose	20	1.8	5.5	200	.035	$199 ea
M00535920	Ultratome XL Short Nose	30	1.8	5.5	200	.035	$199 ea
M00535930	Ultratome XL Long Nose	30	1.8	5.5	200	.035	$199 ea

* Recommended Guidewire .035" Jagwire™ Guidewire, Order #5660, #5661, #5664 or #5665 (see page 9).



■ FLUOROTOME™ SINGLE-USE DOUBLE-LUMEN WIREGUIDED SPHINCTEROTOME (LATEX)

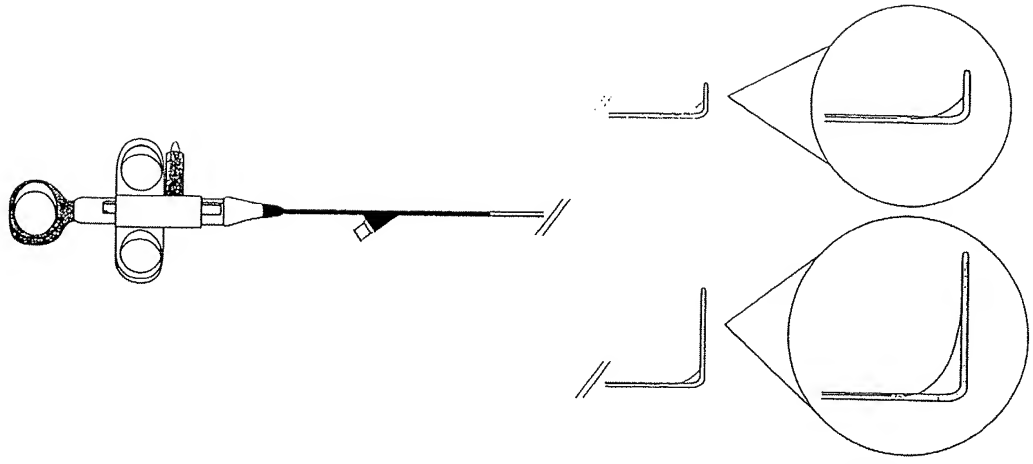
Order Number	Description	Cutting Wire Length (mm)	Distal O.D. (mm)	(Fr)	Catheter Length (cm)	Recommended Guidewire (in)*	Price
M00535800	Fluorotome Short Nose	20	1.8	5.5	200	.035	$195 ea
M00535810	Fluorotome Long Nose	20	1.8	5.5	200	.035	$195 ea
M00535820	Fluorotome Short Nose	30	1.8	5.5	200	.035	$195 ea
M00535830	Fluorotome Long Nose	30	1.8	5.5	200	.035	$195 ea

* Recommended Guidewire .035" Jagwire Guidewire, Order #5658 or #5660 (see page 9).
Active Cords sold separately (see page 23).

(LATEX) Latex-free

2002

SPHINCTEROTOMES



■ ULTRATOME™ SINGLE-USE DOUBLE-LUMEN WIREGUIDED SPHINCTEROTOMES (LATEX)

Order Number	Description	Cutting Wire Length (mm)	Distal O.D. (mm)	Distal O.D. (Fr)	Catheter Length (cm)	Recommended Guidewire (in)*	Price
M00530800	Ultratome Short Nose	20	1.8	5.5	200	.035	$179 ea
M00530810	Ultratome Long Nose	20	1.8	5.5	200	.035	$179 ea
M00530820	Ultratome Short Nose	30	1.8	5.5	200	.035	$179 ea
M00530830	Ultratome Long Nose	30	1.8	5.5	200	.035	$179 ea

* Recommended Guidewire .035" Jagwire™ Guidewire. Order #5658 or #5660 (see page 9).
Active Cords sold separately (see page 23).

(LATEX) Latex Free

EXHIBIT B

Autotome™ RX Cannulating Sphincterotomes

RX Biliary System™

- **Compatible with the RX Biliary System**
  - The Autotome RX Cannulating Sphincterotome is compatible with the RX Biliary System, which is designed to provide secure guidewire access during device advancement, manipulation and exchange

AUTOTOME RX CANNULATING SPHINCTEROTOME*

Order Number	Description	Cut-Wire (mm)	Tip Length (mm)	Tip O.D. (Fr)	Recommended Guidewire (in)
M00545150	Autotome RX 49	20	5	4.9	.035" Hydra Jagwire™ Guidewire
M00545160	Autotome RX 49	30	5	4.9	.035" Hydra Jagwire Guidewire
M00545170	Autotome RX 44	20	5	4.4	.035" Hydra Jagwire Guidewire
M00545180	Autotome RX 44	30	5	4.4	.035" Hydra Jagwire Guidewire
M00545190	Autotome RX 39	20	5	3.9	.025" Jagwire® Guidewire
M00545200	Autotome RX 39	30	5	3.9	.025" Jagwire Guidewire

* Compatible with Universal Active Cords

INSTRUCTIONS FOR USE
Refer to the operator's manual for complete instructions for use.

INDICATIONS
The sphincterotome is indicated for use in transendoscopic sphincterotomy of the Papilla of Vater and/or the Sphincter of Oddi. The sphincterotome can also be used to inject contrast medium.

CONTRAINDICATIONS
Contraindications for this device are those specific to endoscopic retrograde cholanglopancreatography (ERCP) and endoscopic sphincterotomy (ES).

WARNINGS
For single use only. Do not reuse, reprocess or resterilize. Reuse, reprocessing or resterilization may compromise the structural integrity of the device and/or lead to device failure which, in turn, may result in patient injury, illness or death. Reuse, reprocessing or resterilization may also create a risk of contamination of the device and/or cause patient infection or cross-infection, including, but not limited to, the transmission of infectious disease(s) from one patient to another. Contamination of the device may lead to injury, illness or death of the patient.

After use, dispose of product and packaging in accordance with hospital, administrative and/or local government policies.

POTENTIAL ADVERSE EFFECTS
Potential adverse effects include, but may not be limited to: pancreatitis, perforation, hemorrhage, hematoma, cholangitis; septicemia/infection; and allergic reaction to contrast medium.

Any electrosurgical device constitutes a potential electrical hazard to the patient and/or the operator. Possible adverse effects include fulguration, burns, stimulation, and cardiac arrhythmias.

Please be aware that potential adverse effects may arise even with the proper use of medical devices. Accordingly, this device should only be used by persons qualified in the procedures for which it is indicated.

CAUTIONS
Cautions can be found in the product labeling supplied with each device. CAUTION: Federal (USA) law restricts this device to sale by or on the order of a physician.

TRADEMARKS
RX Biliary System, Hydra Jagwire, Jagwire, and Autotome are trademarks of Boston Scientific Corporation or its affiliates.

Boston Scientific

Boston Scientific
Tel 508.650.8000
www.bostonscientific.com

Ordering Information
1.800.225.3226

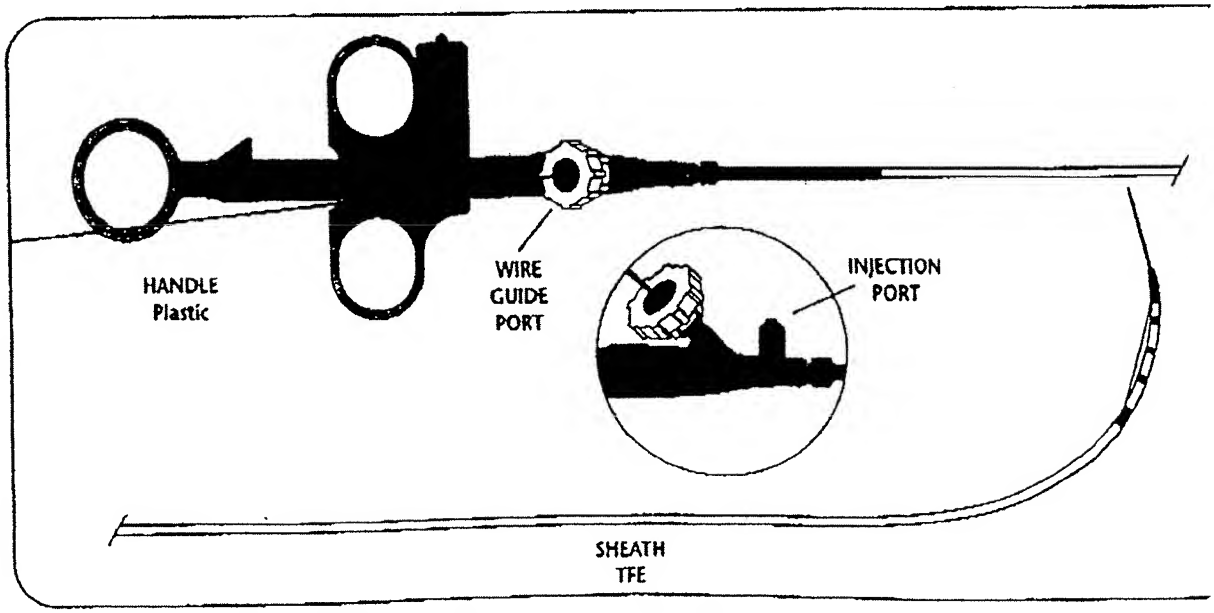
EXHIBIT C

HOWELL DASH™ DIRECT ACCESS SYSTEM

Used for endoscopic cannulation of the ductal system, to aid in bridging difficult strictures during ERCP and for sphincterotomy. The system allows wire guide access to the desired duct during cannulation and sphincterotom Contrast may be injected through an integrated hub. This device is supplied sterile and is disposable – intended for single use only.

DASH-21	6.0 FR catheter tapered to 4.0 FR with cutting wire 21 mm in length (sphincterotome only)	.021 inch*	Black	$225.(
DASH-21-480	5.5 FR catheter tapered to 4.0 FR with cutting wire 21 mm in length Straight tip Metro wire guide, 480 cm length	.021 inch	Black	$225.(
DASH-260 (UPN 13745)	6.0 FR catheter tapered to 4.5 FR with cutting wire 25 mm in length Straight tip Metro wire guide, 260 cm length	.025 inch	Blue	$225.(
DASH-480 (UPN 13747)	6.0 FR catheter tapered to 4.5 FR with cutting wire 25 mm in length Straight tip Metro wire guide, 480 cm length	.025 inch	Blue	$225.(
DASH-1 (UPN 13744)	6.0 FR catheter tapered to 4.5 FR with cutting wire 25 mm in length (sphincterotome only)	.025 inch*	Blue	$125.(
DASH-35-480	7 FR catheter tapered to 5.5 FR with cutting wire 35 mm in length Straight tip Metro wire guide, 480 cm length	.035 inch	Purple	$225.(

*Wire Guide sold separately. U.S. Patent Pending



babytome™

PreCurved Double Lumen Sphincterotomes

for cannulation of the ductal system and for sphincterotomy. This device is supplied sterile and is able - intended for single use only. Active cord available separately.

-25 N 14781)	3.5 FR catheter tapered to 3.0 FR with braided cutting wire 25 mm in length; 7.0 FR introduction catheter tapered to 6.5 FR, 185 cm length	.021 inch	Black	$150.0

*Wire Guide sold separately.

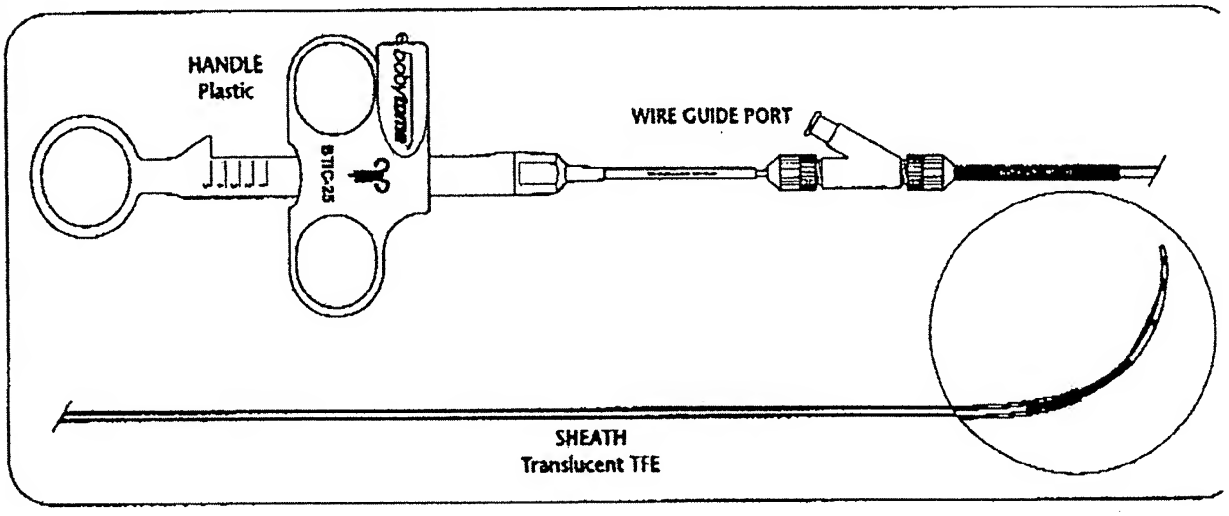
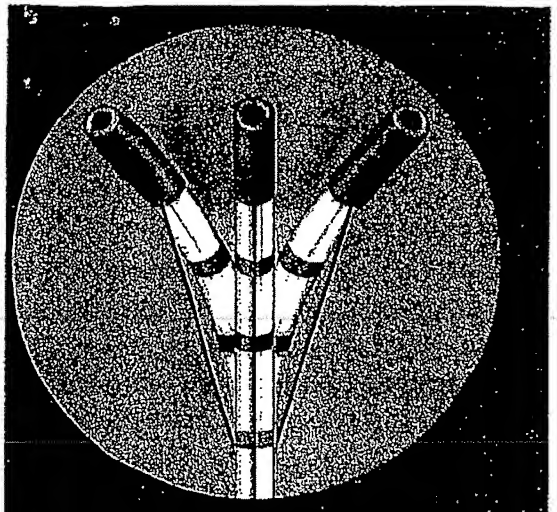
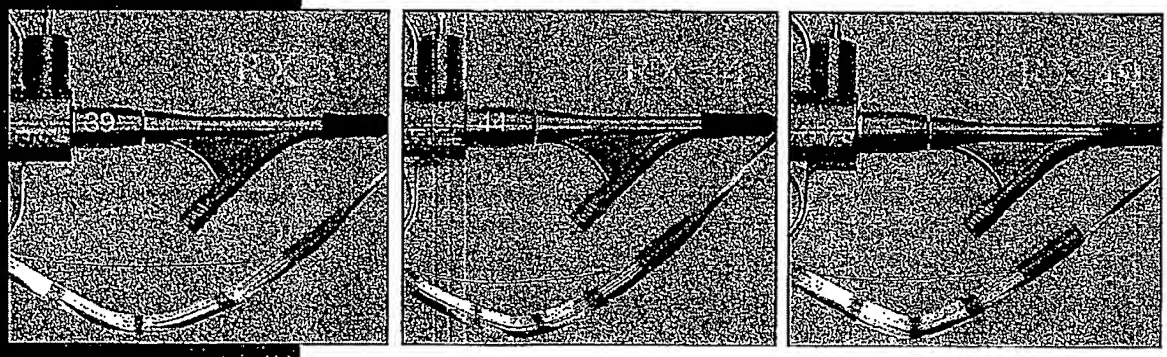


EXHIBIT D



Autotome™ RX Cannulating Sphincterotomes

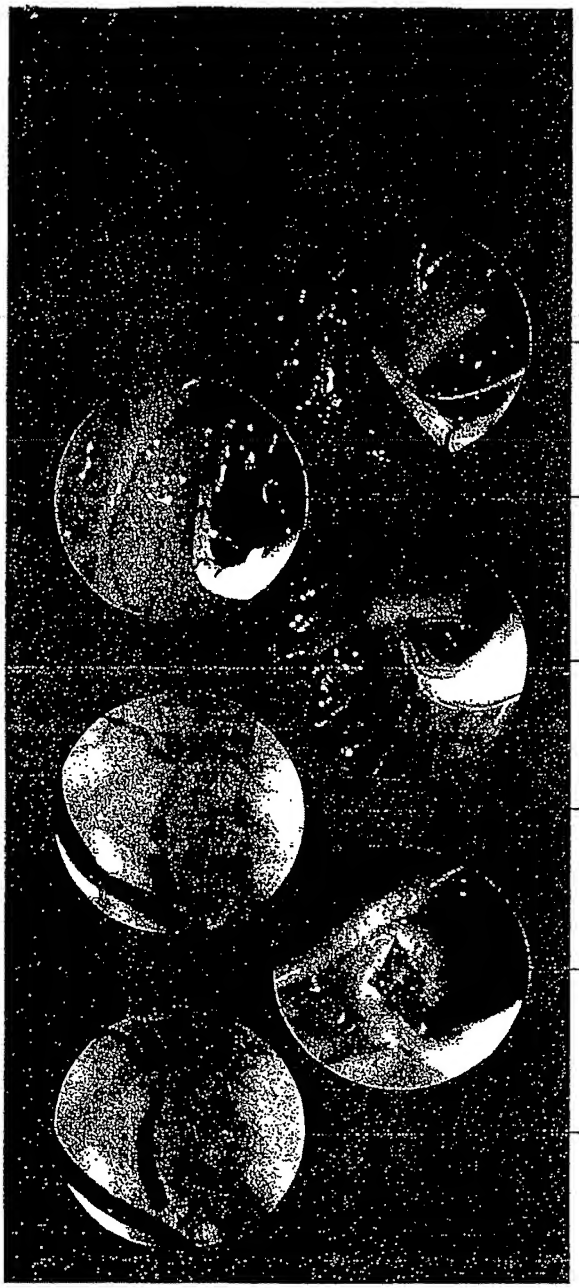
Autotome RX Cannulating Sphincterotomes are full-featured sphincterotomes designed to offer a physician increased tip control and cut-wire positioning after initial scope exit. The reduced short exchange segment facilitates for a more controlled single-operator device withdrawal.



- **RX Compatibility**
  - Enables physician to maintain guidewire control during cannulation and stricture access
  - RX locking device helps maintain secure access during device withdrawal
- **Direct Wire Technology™**
  - Unique design allows for cut-wire positioning to the left or right of the initial scope exit position
- **5 cm Exchange Length**
  - Designed to make a significant reduction of the exchange length over guidewire compared to the non-RX Biliary devices
  - Allows for single-operator device withdrawal
- **Tip Size Variation**
  - Provides a variety of tip sizes for physician preference
  - Handle labeled with respective tip outer diameter for ease of selection (RX 39 and RX 44 only)
- **Merging Lumen Technology™**
  - Allows for contrast injection while maintaining guidewire access in both 4.4 Fr and 3.9 Fr tip sizes
  - 4.4 Fr tip (Autotome™ RX Sphincterotome 44) is designed to be compatible with a 0.035" guidewire
  - May help reduce the risk of submucosal contrast injection by redirecting contrast flow into the guidewire lumen
- **Guidewire Selection**
  - Autotome™ RX 39 is compatible with 0.025" guidewire (0.025" Jagwire Super Stiff guidewire is recommended)
  - Autotome™ RX 49 and RX 44 are compatible with 0.035" guidewire (0.035" Jagwire guidewire is recommended)

physician Control · secure Access · improved Speed · enhanced Efficiency

Boston Scientific



Autotome™ RX Cannulating Sphincterotomes

Richard L. Smith, M.D., Mission St. Joseph's Hospital, Asheville, North Carolina

A 69 year old female presented with apparent gallstone pancreatitis after being hospitalized for a previous injury. After her gallbladder was removed, she was referred for removal of a suspected common duct stone. Due to a previously placed cervical collar, patient positioning was difficult.

The Autotome RX Cannulating Sphincterotome was introduced and exited the scope at the 11 o'clock position.

After failed initial cannulation, the sphincterotome was directed towards the 1 o'clock position to help compensate for difficult patient positioning.

After being directed back to the 12 o'clock position, wireguided cannulation was achieved with physician control of a .035 Jagwire™ guidewire.

Subsequent cholangiogram revealed a 1cm common bile duct stone.

Sphincterotomy was performed with the Autotome RX Cannulating Sphincterotome.

The device was removed in a physician-only exchange. A RX retrieval balloon was then used to clear the duct.

AUTOTOME RX CANNULATING SPHINCTEROTOME*

Product Number	Description	Cut-wire length (mm)	Tip Length (mm)	Tip O.D. (Fr)	Recommended Guidewire
M00545150	Autotome RX 49	20	5	4.9	0.035" Jagwire
M00545160	Autotome RX 49	30	5	4.9	0.035" Jagwire
M00545170	Autotome RX 44	20	5	4.4	0.035" Jagwire
M00545180	Autotome RX 44	30	5	4.4	0.035" Jagwire
M00545190	Autotome RX 39	20	5	3.9	0.025" Jagwire**
M00545200	Autotome RX 39	30	5	3.9	0.025" Jagwire***

* Comparible with Universal Active Cords.
** Recommended 0.035" Jagwire™ guidewire.
***Recommended 0.025" Jagwire™ Super Stiff guidewire.

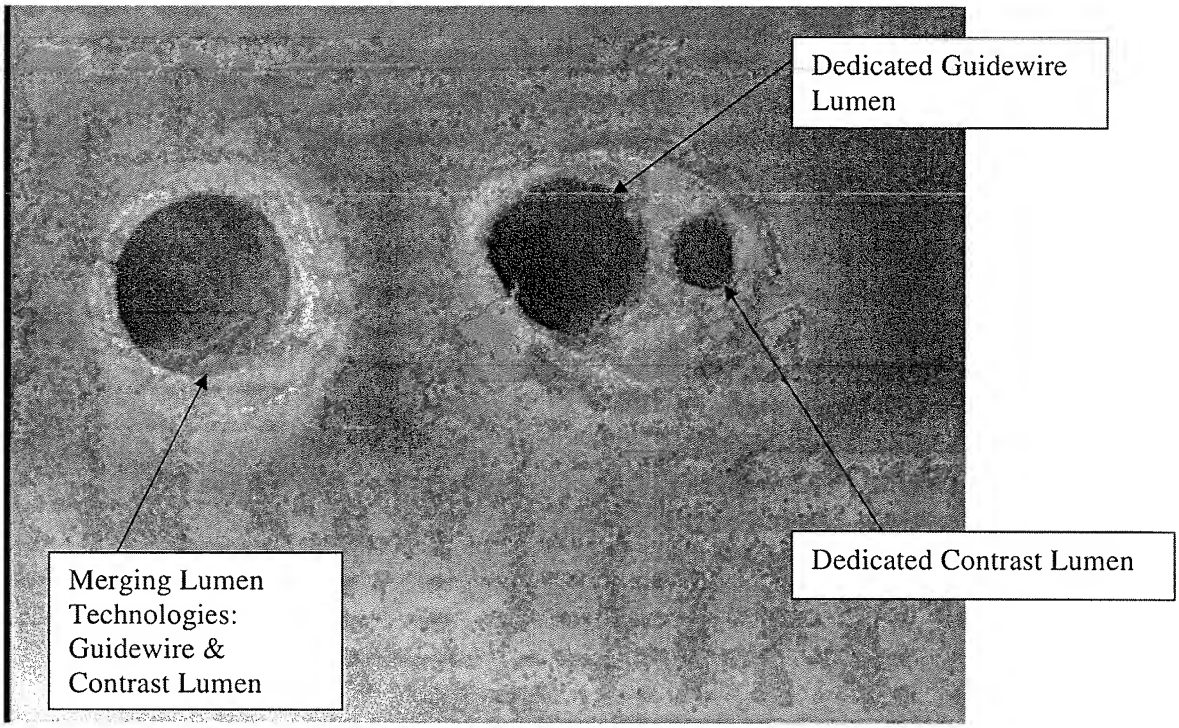
Indications, contraindications, warnings and instructions for use can be found in the product labeling supplied with each device.
CAUTION: Federal (USA) law restricts this devices to sale by or on the order of a physician.

Boston Scientific

Boston Scientific Corporation
Tel 508.650.8000
www.bostonscientific.com

Ordering Information
1.800.225.3225

EXHIBIT E



Boston Scientific
Autotome RX 44
REF No: 4517

ConMed Endoscopic Technologies
Apollo 3 AC
RER No: 7104AC